EXHIBIT 1

David R. Ongaro (State Bar No. 154698)
dongaro@ongaropc.com
Glen Turner (State Bar No. 212417)
gturner@ongaropc.com
ONGARO PC
50 California Street, Suite 3325
San Francisco, CA 94111
Telephone: (415) 433-3900
Facsimile: (415) 433-3950

Attorneys for Plaintiff WAYNE RUDEN

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

WAYNE RUDEN,

Plaintiff,

vs.

C.R. BARD, INC., a New Jersey corporation, BARD PERIPHERAL VASCULAR, INC., (a subsidiary and/or division of defendant C.R. BARD, INC.) an Arizona corporation, CALIFORNIA PACIFIC MEDICAL CENTER, and DOES 1-100 INCLUSIVE,

Defendants.

Case No. 4:15-cv-05189-JSW

Honorable Jeffrey S. White

FIRST AMENDED COMPLAINT FOR DAMAGES

DEMAND FOR JURY TRIAL

Complaint Filed: October 7, 2015

FIRST AMENDED COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

Plaintiff WAYNE RUDEN (the "Plaintiff"), by and through his undersigned attorneys, hereby files his First Amended Complaint ("FAC") against Defendants C.R. BARD, INC.; BARD PERIPHERAL VASCULAR, INC., a subsidiary corporation and/or division of C.R. BARD, INC. (collectively the "Bard Defendants"); California Pacific Medical Center ("CPMC"), and DOES 1 to 100 inclusive (collectively, the "Defendants") and allege as follows:

1. This is an action for damages against the Bard Defendants and Does relating to the development, testing, assembling, manufacture, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling the defective product sold under the name "inferior vena cava filter" (hereinafter "IVC filter").

2. Plaintiff files this FAC pursuant to Federal Rule of Civil Procedure 15.

3. This is an action for damages against all Defendants relating to the supplying, providing, implanting and/or selling the defective IVC filter and failure to reasonably disclose or to reasonably inform Plaintiff Wayne Ruden of defects which were known or apparent at the time of implantation or that became known or apparent at a later date, in derogation of duties to provide reasonable professional care or to uphold fiduciary and confidential duties to the Plaintiff.

PARTIES

Plaintiff

4. Plaintiff, Wayne Ruden, is and has at all pertinent times been a resident of San Francisco, California, which is located in the City and County of San Francisco, California.

5. Venue is proper in the Superior Court of California, County of San Francisco as a substantial part of the events or omissions giving rise to the claim occurred within this County, Defendant CPMC has a principal place of business in this County, and the Defendants regularly conduct business in that County.[1]

Defendants

[1] Plaintiff will timely file a motion to remand this action to the Superior Court of California, County of San Francisco.

6. The true names and capacities, whether individual, corporate, associate, governmental or otherwise, of Defendants DOES 1 through 100, inclusive, are unknown to Plaintiff at this time, who therefore sues said Defendants by such fictitious names. When the true names and capacities of said Defendants have been ascertained, Plaintiff will amend this complaint accordingly. Plaintiff is informed and believes, and thereon alleges, that each Defendant designated herein as a DOE is responsible, negligently or in some other actionable manner, for the events and happenings hereinafter referred to, and caused injuries and damages proximately thereby to the Plaintiff, as hereinafter alleged.

7. At all times herein mentioned, each of the Defendants was the agent, servant, partner, licensee and licensor, aider and abettor, co-conspirator, employee and/or joint venture of its co-Defendants, and each of them, and at all said times each Defendant was acting in the full course and scope of said agency, service, employment, partnership, conspiracy, license, and/or joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that its conduct constituted breach of duty owed to Plaintiffs. Plaintiffs are informed and believe, and thereon allege that at all times herein mentioned, Defendants **C.R. BARD, INC., DEFENDANT BARD PERIPHERAL VASCULAR, INC., DEFENDANT CALIFORNIA PACIFIC MEDICAL CENTER and DOES 1-100 INCLUSIVE** were individuals, corporations, partnerships and/or unincorporated associations organized and existing under and by virtue of the laws of the State of California, or the laws of some other state or foreign jurisdiction, and that said Defendants, and each of them, were and are authorized to do and are doing business in the State of California.

8. Defendant C.R. Bard, Inc. ("Bard") is a corporation duly organized and existing under the laws of the state of Delaware and has its principal place of business in New Jersey. Bard, at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the Bard Recovery Filter ("BRF") to be implanted in patients throughout the United States, including California. At all times relevant hereto, Defendant Bard was or has been engaged in business in California, and has conducted substantial business activity in California. Defendant has also carried on

solicitations or service activities in the State of California.

9. Defendant Bard Peripheral Vascular, Inc. ("BPV") is a wholly owned subsidiary corporation of defendant Bard, with its principal place of business at 1625 West 3rd Street, Tempe, Arizona. BPV at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the BRF to be implanted in patients throughout the United States, including California. At all times relevant hereto, Defendant BPV was or has been engaged in business in California, and has conducted substantial business activity in California. Defendant has also carried on solicitations or service activities in the State of California.

10. California Pacific Medical Center ("CPMC") is a general medical and surgical hospital and academic medical center operating at multiple locations in San Francisco, California. Mr. Ruden was a CPMC patient when the decision was taken to implant a BRF in his body, was an ongoing CPMC patient thereafter, and was hospitalized and/or seen in consultation at CPMC multiple times between 2004, when the device was implanted, and 2015, when Mr. Ruden's physicians discovered that it had fractured and that metal fragments had embolized into his heart and lungs. CPMC knew at all pertinent times that the BRF was defective and unreasonably dangerous and was causing injury and death to patients who received it or, in the alternative, Bard concealed dangers known to Bard from CPMC.

11. CPMC knew the BRF was defective and unreasonably dangerous and was causing injury and death to patients who received it or, in the alternative, Bard concealed dangers known to Bard from CPMC.

12. A BRF was implanted in plaintiff's body in March 2004. CPMC already knew at that time of implementation, but failed to inform Plaintiff, that the device had hidden dangers, including a high rate of fracture, migration, and excessive tilting and perforation of the wall of the inferior vena cava, typically leading to serious injury or, in the alternative, CPMC was not fully aware of the BRF's dangerous and defective nature at that time because Bard had failed to fully inform CPMC.

13. CPMC failed to insure that its agent and employee care providers were adequately

trained to perform their relevant duties, including their duty to reasonably inform themselves of the risks of utilizing the BRF as part of Mr. Ruden's treatment, and subsequently failed to adequately inform Mr. Ruden of its dangers, either prior to or subsequent to the insertion of the BRF into Mr. Ruden's body.

14. CPMC had an ongoing duty to reasonably warn Plaintiff of newly-discovered risks. However, CPMC did not communicate to Mr. Ruden a FDA 2010 warning letter regarding dangers of IVC filters, especially when left in situ over a long period. CPMC had previously learned, over the years between the insertion of the BRF into Mr. Ruden's body in 2004 and the 2010 date of the warning letter, of the numerous adverse incidents cited in the FDA's 2010 warning and failed to communicate the newly-discovered danger to Mr. Ruden or, in the alternative, CPMC was not fully aware of the BRF's dangerous and defective nature because Bard failed to fully inform CPMC as it gradually became aware of said risks. At all relevant times, Bard negligently provided Plaintiff and his health care providers with false or incorrect information or omitted material information regarding dangers of the BRF, and Plaintiff's health-care providers negligently relied on Bard's misrepresentations.

JURISDICTION AND VENUE

15. Pursuant to plaintiff's motion to remand to be filed in this action, jurisdiction is proper in the Superior Court of California, County of San Francisco because each defendant has engaged in and conducted substantial business activity in California, two parties are residents of the State of California, and because all of the events and omissions giving rise to liability in this matter occurred in California. The Bard defendants manufactured and sold the BRF, which entered California through the stream of commerce into San Francisco, California. CPMC is located in San Francisco, California, the decision to insert the BRF in plaintiff's body was made in the City and County of San Francisco, and various of the breaches, malfeasance, bad acts and omissions alleged herein occurred in the City and County of San Francisco.

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A. GENERAL FACTUAL ALLEGATIONS (ALL DEFENDANTS AND

DOES 1-100 INCLUSIVE)

16. Plaintiff brings this case for serious and permanent injuries he suffered as a result of a surgically implanted medical device, known as a Bard Recovery Filter, which fractured, resulting in the embolization of two arm fragments into the proximal right pulmonary arteries, and the embolization of one fractured arm fragment into the right atrium of his heart, where it remains to this day. Any operation to remove the fragments would subject plaintiff to a heightened risk of permanent injury, including chance of death.

17. The BRF was designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold by Defendants for prevention of blood clots (thrombi) from traveling from the lower portions of the body to the heart and lungs.

18. Prior to Plaintiff Wayne Ruden being implanted with a BRF on or about March 2004, Defendants knew or should have known that the device was defective and unreasonably dangerous for, *inter alia*, the following reasons:

a. The Bard defendants failed to conduct any clinical testing, such as animal studies, to determine how the device would function once permanently implanted in the human body.

b. Defendants knew and/or should have known that the BRF had a high rate of fracture, migration, and excessive tilting and perforation of the vena cava wall once implanted in the human body. Defendants know and/or should have known that such failures exposed patients to serious injuries, including: death; hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; perforations of tissue, vessels, and organs; and inability to remove the device. Further, Defendants knew and should have known that these risks for the BRF were and are substantially higher than other similar devices.

c. Further, Defendants knew and/or should have known that the BRF contained conditions which Defendants did not intend, which resulted in the device not performing as safely as the ordinary customer would expect.

d. Despite being aware of these risks, Defendants misrepresented, omitted, and/or failed to provide adequate warnings of these risks or instructions for safe use.

e. Even when the Bard designed and began marketing what they alleged to be a device that specifically reduced these risks, they still failed to issue a recall or notify consumers that a safer device was available.

INFERIOR VENA CAVA FILTERS GENERALLY

19. The IVC filter at issue in this case was manufactured, marketed, and sold by the Bard Defendants, C.R. Bard, Inc. and/or Bard Peripheral Vascular, Inc., at all pertinent times. "Bard Defendants" continue to manufacture and sell the BRF's successor, the G2 device, throughout the United States of America and abroad.

20. IVC Filters first came on the medical market decades ago. Over the years, several different medical device manufacturers have introduced several different designs of IVC filters.

21. An IVC filter is a device that is designed to filter or "catch" blood clots (called "thrombi") that travel from the lower portions of the body to the heart and lungs. IVC filters may be designed to be implanted, either permanently or temporarily, in the human body, more specifically, within the inferior vena cava.

22. The inferior vena cava is a vein that returns blood to the heart from the lower portions of the body. In certain people, for various reasons, thrombi travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. Oftentimes, these thrombi develop in the deep leg veins. These thrombi are called "deep vein thrombosis" or "DVT." Once thrombi reach the lungs, they are considered "pulmonary emboli" or "PE." Pulmonary emboli present grave risks to human health.

23. Certain people are at increased risk for the development of DVT or PE. Those people at risk for DVT/PE can undergo medical treatment to manage the risk. For example, a doctor may prescribe medications like Heparin, Warfarin, or Lovenox to regulate the clotting factor of the blood. In some people who are at high risk for DVT/PE, or who cannot manage their conditions with medications, physicians may recommend surgically implanting an IVC filter to prevent thromboembolic events.

24. Over the years, a concern developed within the medical community (and was

shared by IVC filter manufacturers) that an IVC filter should be designed and manufactured so that it can be retrieved from the human body. Eventually, retrievable IVC filter designs were offered in the market. However, these IVC filter designs were not intended to remain within the human body for indeterminate periods of time. In other words, the initial designs of retrievable IVC filters were intended to remain implanted for a finite period of time. The BRF (discussed in more detail *infra*) was introduced to the market in late 2002 or 2003 (and subsequently removed from the market in late 2005) as an IVC filter that was able to be retrieved after an indeterminate time of placement within the human body.

THE BARD RECOVERY FILTER

25. The BRF is a medical device constructed of a nickel-titanium alloy (also called "Nitinol") designed to filter blood clots (thrombi) from the human circulatory system. Nitinol material is unique. Nitinol is actually an acronym that stands for Nickel Titanium Naval Ordnance Laboratory. Nitinol is also unique as it possesses "shape memory." That is, Nitinol will change shape according to change in temperature, and then, retake its prior shape after returning to its initial temperature. This quality makes Nitinol appealing for use in certain medical devices, including IVC Filters.

26. Soon after the BRF's introduction to the market, reports were made that portions of the device were fracturing and migrating to the anatomy and vital organs of the patients in whom it was implanted. These reports continued to surface and were made to healthcare providers, the FDA, and to the Defendants. In fact, as early as 2003, the Defendants were made aware that the BRF was flawed and was causing injury and death to patients who had the filter implanted in their bodies.

27. The BRF was plagued with manufacturing and design defects which caused it to experience a significant rate of fracture and migration of the device. Studies performed in the medical and scientific communities established that the BRF had a 21% to 31.7% rate of fracture.

28. The failure of the BRF, as aforesaid, was attributable, in part, to the fact that the BRF was not designed so as to be able to withstand the normal anatomical and physiological

loading cycles exerted *in vivo*.

29. Sometime after 2003, the Defendants made a decision to introduce a substitute vena cava filter for Bard Peripheral Vascular's vena cava filter product line. This substitute vena cava filter was meant to replace the BRF. It was to be called the "G2 Filter." G2 stands for "second generation."

30. In 2005, the Defendants submitted an application to the Food and Drug Administration ("FDA") for introduction of the G2™ Filter to the global market. The application was submitted under Section 510(k) of the United States Food, Drug and Cosmetic Act ("Act") of 1976 (21 U.S.C. 321 *et seq*. Under Section 510(k), a medical device manufacturer may represent that the device which is offered for approval is "substantially similar" to a "predicate device." With regard to the G2 Filter, the Defendants represented to the F.D.A that it was substantially similar to the Recovery™ Filter System (the predicate device).

31. The Defendants first received clearance from the FDA to market the G2™ Filter System as a permanent placement vena cava filter. The Defendants began selling the G2™ Filter System in September of 2005. Later, in 2008, the G2™ Filter was cleared by the FDA as a retrievable (option) IVC filter.

BRF FAILURE RESULTS IN FATAL CONSEQUENCES

32. The failure (fracture and/or migration) of the BRF leads to a number of different, and potentially fatal, complications. These complications include, but are not limited to:

a. Death;

b. Hemorrhage;

c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);

d. Severe and persistent pain; and

e. Perforation of tissue, vessels and organs.

33. The person who experiences failure (fracture and/or migration) of the BRF often experiences an acute onset of chest pain and shortness of breath. This typically results

in the person presenting to an emergency room, hospital, and/or physician for evaluation.

34. The BRF was placed in Plaintiff's body on or about March 2004. Plaintiff discovered for the first time on or about March 2015 that the BRF had fractured, injuring him by causing the embolization of two arm fragments into the proximal right pulmonary arteries, and the embolization of one fractured arm fragment into the right atrium of his heart. Plaintiff has incurred significant medical expenses and has endured extreme pain and suffering, fear of death, loss of enjoyment of life, and other losses, some of which are permanent in nature. As a result of the failure of the BRF, Plaintiff lives in constant fear that the BRF will continue to migrate, pierce his heart, and kill him. Plaintiff has become impaired and his ability to earn wages has been diminished, and will remain so in the future. The defective BRF remains in Plaintiff's body. Plaintiff is required to attend regular physicians' visits and to undergo imaging studies in order to monitor the threats of death, and/or permanent disability, related to the fractured BRF.

35. As a direct and proximate result of the conduct and defective product of the Bard Defendants, as alleged in this Complaint, and of the failure by Defendant CPMC to disclose information about said defective product that it had a duty to disclose, Plaintiff Wayne Ruden has suffered permanent and continuing injury, loss of enjoyment of life, pain, suffering, and impairment. Plaintiff has suffered emotional trauma, harm and injuries. Plaintiff's ability to carry on the affairs of his daily life has been impacted and diminished, and will continue to diminish in the future.

36. As a direct and proximate result of the conduct and defective product of the Defendants, as alleged in this Complaint, medical monitoring is necessary for Plaintiff Wayne Ruden. Medical monitoring includes:

a. Regularly scheduled CT scans or other appropriate imaging studies; and/or

b. Potential cardiac catheterization or other endovascular procedure to detect the presence of migrated pieces of the BRF; and or physicians' visits and examinations.

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DEFENDANTS KNEW OF THE DANGERS, INCLUDING DEATH, RELATED TO

THE BRF

37. Upon information and belief, Plaintiff alleges that, at all pertinent times including prior to the implantation of the BRF in Plaintiff in March 2004 the Bard Defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., including the officers, directors and managing agents Timothy M. Ring, John H. Weiland, Christopher S. Holland, Jim C. Beasley, Timothy P. Collins, Sharon M. Luboff, John P. Groetelaars, John A. DeFord, Samrat S. Knichi, Patricia G. Christian, Andrea J. Casper, Todd W. Garner, Scott T. Lowry, Betty Larson, Frank Lupisella, Jr., Patrick D. Roche and Richard C. Rosenzweig were aware and had knowledge of the fact that the BRF was defective and unreasonably dangerous and was causing injury and death to patients who had received the BRF.

38. Upon information and belief, CPMC was also aware at all pertinent times including prior to the implantation of the BRF in Plaintiff in March 2004, of the fact that the BRF was defective and unreasonably dangerous and was causing injury and death to patients who had received the BRF, Bard unreasonably failed to communicate these dangers to CPMC and the public.

39. Upon information and belief, the Bard defendants caused regulatory approval to be obtained for the device through deceptive means, and with full knowledge of its dangerous propensities and unacceptable failure rate.

40. Upon information and belief, Plaintiff alleges that CPMC was aware and had knowledge of the fact that the BRF was defective and unreasonably dangerous and was causing injury and death to patients who had received the BRF.

41. Data established that the failure rate of the BRF was/is exceedingly higher than the rates the Defendants have published in the past, and currently continue to publish to the medical community, members of the public, and the FDA.

42. Over 921 adverse events were identified by the FDA through a warning issued in August of 2010 regarding risks associated with IVC filter complications.

43. Upon information and belief, from the time the BRF became available on the market, the Bard Defendants embarked on an aggressive campaign of "off-label marketing"

concerning the BRF. This included representations made to physicians, healthcare professionals, and other members of the medical community that the BRF was safe and effective for retrievable use prior to the FDA clearing the BRF for retrievable use in 2008.

44. The conduct of the Bard Defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. as alleged in this First Amended Complaint, constituted willful, wanton, gross and outrageous corporate conduct that demonstrates a conscious disregard for the safety of the Plaintiff Wayne Ruden. The Bard Defendants had actual knowledge of dangers to the life health and well-being of the Plaintiff Wayne Ruden presented by the BRF, yet consciously failed to act reasonably to:

a. Inform or warn the Plaintiff, his physicians, or the public at large of the dangers; and

b. Recall the BRF from the market in a timely and safe fashion.

45. Despite having knowledge at all pertinent times of the unreasonably dangerous and defective nature of the product, the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. consciously disregarded the known risks, failed to warn physicians and users of the health risk, including death, of long-term retention of the device, fraudulently obtained FDA approval for the IVC devices and continued to actively market and offer for sale the BRF:

a. Bard Defendants were aware and had full knowledge that the IVC devices were associated with approximately thirty deaths and three-hundred injuries between 2004 and 2015, upon information and belief;

b. Bard Defendants retained an experienced regulatory specialist, Kay Fuller, who possessed nearly thirty years of experience in the medical device industry, in 2002 to assist Bard Defendants to obtain FDA approval for the IVC / BRF devices after the Bard Defendants' previous attempts to gain FDA approval failed because the devices were defective;

c. Upon information and belief, Bard Defendants failed to provide Ms. Fuller results of a safety performance test related to IVC / BRF, and further, Ms. Fuller expressed concerns to directors, officers and/or managing agents of Bard Defendants that human clinical trials for IVC / BRF were below acceptable standards. Bard Defendants did not adequately investigate, follow up,

or otherwise analyze any potential health related concerns with the IVC / BRF, despite Ms. Fuller's protests and requests for the same investigations;

d. Upon information and belief, and despite Ms. Fuller's protests, the Bard Defendants proceeded in their attempt to obtain FDA approval. However, Ms. Fuller refused to sign the FDA application for the IVC / BRF approval. Clinical studies indicated serious risks related to the IVC / BRF and the Bard Defendants failed to disseminate this information to Plaintiff, and other patients. Regardless, the Bard Defendants submitted an FDA application and Ms. Fuller subsequently denied that she signed any FDA application on behalf of the Bard Defendants;

e. Subsequent to the Bard Defendants' submission of the application to the FDA regarding IVC / BRF approval, Ms. Fuller resigned from her employment with the Bard Defendants; and,

f. As early as 2004, medical studies indicated the IVC / BRF had a higher rate of relative risk for death, filter fracture and movement than all of its competitors; accordingly, further investigation of the safety of the IVC / BRF was warranted.

46. Plaintiff further alleges that the Bard Defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., acted in a willful, wanton and gross manner, and in total disregard for the health and safety of the users or consumers of its BRF, including Plaintiff Wayne Ruden, and acted to serve their own interests and consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons. Therefore, Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. should be liable for a punitive or exemplary damage award to the Plaintiff.

DUTY OF DEFENDANT CPMC TO ENSURE REASONABLE CARE

47. CPMC had a duty to exercise reasonable care to plaintiff. Further, CPMC breached its duty to monitor plaintiff's condition after implantation of the BRF. In addition, CPMC violated its duty to screen its own medical staff, physicians and agents for competency to administer and monitor patients who were treated with the BRF, and to learn pertinent facts about the BRF and then determine whether the BRF was reasonably safe for clinical use.

48. Further, CPMC had a duty to disclose material information to plaintiff regarding

the BRF. Doctors, treaters, nurses and agents were not adequately informed, trained or given relevant information regarding the potential for failure of the BRF. Moreover, before 2004 it was known by CPMC and Bard Defendants that the BRF was defective and could fail, or in the alternative, Bard Defendants unreasonably failed to make known to CPMC pertinent information about the dangerous propensities of the BRF. Despite knowledge of failures of the BRF prior to 2004, CPMC and Bard Defendants failed to provide any material information regarding the defects and failure of BRF to plaintiff.

FIRST CAUSE OF ACTION: NEGLIGENCE

(BARD DEFENDANTS AND DOES 1-100 INCLUSIVE)

49. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

50. At all times relevant to this cause of action, the Bard Defendants were in the business of designing, developing, setting specifications, manufacturing, marketing, selling, and distributing the BRF.

51. The Bard Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed and sold the BRF that was implanted in Plaintiff.

52. The Bard Defendants had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the BRF so as to avoid exposing others to foreseeable and unreasonable risks of harm.

53. At the time the BRF was implanted in Plaintiff's body, all Defendants knew or reasonably should have known that the BRF was dangerous or was likely to be dangerous when used in its intended or reasonably foreseeable manner.

54. At the time of manufacture and sale of the BRF, the Bard Defendants knew or should have known that the BRF:

a. Was designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device;

b. Was designed and manufactured so as to present an unreasonable risk of

migration of the device and/or portions of the device; and/or

c. Was designed and manufactured so as to present an unreasonable risk of the device tilting and/or perforating the vena cava wall; and/or

d. Was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body.

55. At the time of manufacture and sale of the BRF, the Bard Defendants knew or should have known that using the BRF in its intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe health side effects, including, but not limited to: hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels and organs; and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the device; and the continued risk of requiring additional medical and surgical procedures including general anesthesia, with attendant risk of life threatening complications.

56. At the time the BRF was implanted in Plaintiff's Body, all Defendants knew or reasonably should have known that consumers of the BRF would not realize the danger associated with using the device in its intended use and/or in a reasonably foreseeable manner.

57. The Bard Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the BRF in, among other ways, the following acts and omissions:

a. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

b. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other device available for the same purpose;

c. Failing to use reasonable care in manufacturing the product and producing a

product that differed from their design or specifications or from other typical units from the same production line;

d. Failing to use reasonable care to warn or instruct, including pre- and post-sale, Plaintiff, Plaintiff's physicians, or the general health care community about the BRF's substantially dangerous condition or about facts making the product likely to be dangerous;

e. Failing to perform reasonable pre and post-market testing of the BRF to determine whether or not the product was safe for its intended use;

f. Failing to provide adequate instructions, guidelines, and safety precautions, including pre- and post-sale, to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the BRF;

g. Advertising, marketing and recommending the use of the BRF, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with and inherent in the use of the BRF;

h. Representing that the BRF was safe for its intended use when in fact, Defendants knew and should have known the product was not safe for its intended purpose;

i. Continuing manufacture and sale of the BRF with the knowledge that said product was dangerous and not reasonably safe, and failing to comply with good manufacturing regulations of the Food and Drug Administration;

j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the BRF so as to avoid the risk of serious harm associated with the use of the BRF;

k. Advertising, marketing, promoting and selling the BRF for uses other than as approved and indicated in the product's label;

l. Failing to establish an adequate quality assurance program used in the manufacturing of the BRF; and

m. Failing to establish and maintain an adequate post-market surveillance program.

58. A reasonable manufacturer, distributor, seller or medical provider under the same or similar circumstances would not have engaged in the before-mentioned acts and omissions.

59. As a direct and proximate result of the foregoing negligent acts and omissions by Defendants, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

SECOND CAUSE OF ACTION: NEGLIGENCE

(CPMC AND DOES 1-100 INCLUSIVE)

60. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

61. CPMC, through its own acts and the acts of its agents, created a fiduciary or special relationship with the Plaintiff when they and their agents recommended and advised the insertion of a BRF in Plaintiff, and when they and their agents inserted a BRF in Plaintiff on or about March 2004. The agents of CPMC consisted of the physicians employed by and/or associated with CPMC, including Dr. Edwin Hassid, Dr. Sung Choi, Dr. William Kuo, Dr. Bertrand Tuan, nurses, officers, directors, attendants and other employees of CPMC that decided, directed and/or performed the BRF procedure on Plaintiff.

62. The implantation of the BRF in Plaintiff created a danger, which arose from the fiduciary or special relationship between CPMC and its physicians, agents, employees and plaintiff.

63. CPMC therefore had an ongoing duty to reasonably warn the Plaintiff of newly-discovered risks related to this danger based on their fiduciary and special relationship with the Plaintiff.

64. On August 9, 2010, the FDA issued a warning letter regarding IVC filters, reporting 921 adverse events associated with the devices which had occurred by that time. The FDA advised that the events could be related to a retrievable filter remaining in the body for long periods of time.

65. The FDA advised treaters, such as CPMC and its agents, to consider the risks and benefits of filter removal for each patient.

66. On information and belief, CPMC received this warning. On information and belief, CPMC was informed by Bard as adverse events associated with the BRF occurred during

the period between 2004 and 2010 or, in the alternative, Bard unreasonably failed to inform CPMC and the general public of those adverse events.

67. CPMC failed to communicate with the Plaintiff either about the FDA warning or about the adverse events underlying the warning, including by requesting that he undergo reasonable imaging examinations to determine the status of the BRF in his body or by asking him to undergo other appropriate and reasonable testing or examination or by providing information related to his health.

68. CPMC, by and through its agents, physicians, nurses and employees did not act with reasonable care when it failed to communicate with the Plaintiff in said fashion. CPMC's failure to use reasonable care was gross, oppressive and malicious.

THIRD CAUSE OF ACTION

STRICT PRODUCTS LIABILITY - FAILURE TO WARN

(BARD DEFENDANTS AND DOES 1-100 INCLUSIVE)

69. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

70. The Bard Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed and sold the BRF, including the one implanted into Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers.

71. At the time the Bard Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, the Bard Defendants knew or should have known the device presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use.

72. Defendants knew or should have known at the time the BRF was implanted in Plaintiff, that the BRF, *inter alia*, posed a significant and higher risk than other similar devices of device failure (fracture, migration, tilting, and perforation of the vena cava wall) and resulting serious injuries.

73. Therefore, Defendants had a duty to warn of the risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device. Defendants further had a duty to warn of dangers and proper safety instructions that it became aware of even after the device was distributed and implanted in Plaintiff.

74. Despite this duty, Defendants failed to adequately warn of material facts regarding the safety and efficacy of the BRF, and further failed to adequately provide instructions on the safe and proper use of the device.

75. No health care provider, including Plaintiff's physicians, or patient would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers and/or ultimate users of the device.

76. The health risks associated with the device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

77. Plaintiff and Plaintiff's health care providers used the device in a normal, customary, intended, and foreseeable manner, namely as a surgically implanted device used to prevent pulmonary embolisms.

78. After it was implanted, the device continued to function in a normal, customary, intended, and foreseeable manner, namely as a surgically implanted device used to prevent pulmonary embolisms.

79. Therefore, the BRF implanted in Plaintiff was defective and unreasonably dangerous at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

80. The BRF implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by the Bard Defendants.

81. As a direct and proximate result of Defendants' lack of sufficient warning and/or instructions, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

FOURTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY –

DESIGN DEFECT – CONSUMER EXPECTATION

(BARD DEFENDANTS AND DOES 1-100 INCLUSIVE)

82. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

83. At all times relevant to this action, the Bard Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed and sold into the stream of commerce the BRF, including the one implanted in Plaintiff.

84. The BRF was expected to, and did, reach its intended consumers without substantial change in the condition in which it was in when it left Defendants' possession. In the alternative, any changes that were made to the BRF implanted in Plaintiff were reasonably foreseeable to Defendants.

85. The BRF implanted in Plaintiff was defective in design because it failed to perform as safely as an ordinary consumer would have expected it to perform at the time of use.

86. The BRF implanted in Plaintiff was defective in design, in that its risks of harm exceeded its claimed benefits.

87. Plaintiff and Plaintiff's health care providers used the BRF in a manner that was reasonably foreseeable to and intended by Defendants.

88. Plaintiff could not by the exercise of reasonable care discovered the device's defective condition or perceived its unreasonable dangers prior to implantation with the device. The Bard Defendants and CPMC had knowledge of the defects in the BRF.

89. As a direct and proximate result of the BRF's defective design, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, ongoing fear and dread, disability, and other losses, in an amount to be determined at trial.

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FIFTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY –

DESIGN DEFECT – RISK-BENEFIT TEST

(BARD DEFENDANTS AND DOES 1-100 INCLUSIVE)

90. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

91. At all times relevant to this action, the Bard Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed and sold into the stream of commerce the BRF, including the one implanted in Plaintiff.

92. As a direct and proximate result of the BRF's defective design, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, ongoing fear and dread, disability, and other losses, in an amount to be determined at trial.

93. The BRF implanted in Plaintiff was defective in design, in that its risks of harm exceeded its claimed benefits

94. The BRF implanted in Plaintiff was defective in design because it was not designed to withstand the stress of long-term implantation *in vivo*.

95. The BRF implanted in Plaintiff was defective in design because of the unacceptably high risk of fracture and fragmentation.

96. The BRF implanted in Plaintiff was defective in design, because, on information and belief, safer alternative designs existed. An example is the inferior vena cava filter designs used by other manufacturers that did not result in such a high fragmentation rate.

97. The BRF implanted in Plaintiff was defective in design because, on information and believe, the cost of an alternative design was less than the grave risk of releasing the product onto the market in the state it was released.

SIXTH CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(BARD DEFENDANTS AND DOES 1-100 INCLUSIVE)

98. Plaintiff re-alleges and incorporate by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

99. The Bard Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the BRF that was implanted into Plaintiff.

100. The BRF implanted in Plaintiff contained a condition, which Defendants did not intend at the time it left Defendants' control and possession. The BRF was defectively manufactured because it fractured, disassembled and failed to perform as intended or expected by the consumer. Shards of metal reside in plaintiff's heart and surrounding tissue. Each shard presents a threat to plaintiff's life and plaintiff has endured pain and suffering as a result of Defendants' manufacturing defect.

101. Plaintiff and Plaintiff's health care providers used the BRF in a manner that was reasonably foreseeable to Defendants.

102. The BRF injured Plaintiff and failed to perform as safely as an ordinary consumer would expect when used in a reasonably foreseeable manner.

103. As a direct and proximate result of the BRF's manufacturing defect, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

SEVENTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

(ALL DEFENDANTS AND DOES 1-100 INCLUSIVE)

104. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

105. At all times relevant to this cause, and as detailed *supra*, Defendants negligently provided Plaintiff, Plaintiff's health care providers, and the general medical community with false or incorrect information, or omitted or failed to disclose material information concerning the BRF, including, but not limited to, misrepresentations of material fact relating to the following subject areas:

a. The safety of the BRF;

b. The efficacy of the BRF;

c. The rate of failure of the BRF;

d. The approved uses of the BRF.

106. The information distributed by the Defendants to the public, the medical community and Plaintiff's health care providers was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the BRF. CPMC failed to properly screen or inquire as to these misrepresentations and passed these misrepresentations along to Plaintiff's health care providers, through their agents, physicians employed and/or associated with CPMC, including Dr. Edwin Hassid, Dr. Sung Choi, Dr. William Kuo, Dr. Bertrand Tuan, nurses, officers, directors, attendants and other employees. Defendants made the foregoing misrepresentations knowing that they were false or without reasonable basis. Plaintiff was reasonable to believe the assertions of Defendants regarding the putative safety of the BRF. On information and belief, these materials included instructions for use and warning in a document that was included in the package of the BRF that was implanted in Plaintiff. Defendants possessed a legal duty to communicate accurate information to Plaintiff regarding known, or knowable, risks regarding surgical implantation of BRF.

107. The Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff's health care providers; to gain the confidence of the public and the medical community, including Plaintiff's health care providers; to falsely assure them of the quality of the BRF and its fitness for use; and to induce the public and the medical community, including Plaintiff's healthcare providers, to request, recommend, prescribe, implant, purchase, and continue to use the BRF.

108. The foregoing representations and omissions by Defendants were false. The BRF is not safe, fit, and effective for human use in its intended and reasonably foreseeable manner. The use of the BRF is hazardous to the user's health, and said device has a serious propensity to cause users to suffer serious injuries, including without limitation, the injuries Plaintiff suffered. Further, the device has a significantly higher rate of failure and injury than do other comparable

devices.

109. In reliance upon the false and negligent misrepresentations and omissions made by Defendants, Plaintiff and Plaintiff's health care providers were induced to, and did use the BRF, thereby causing Plaintiff to sustain severe and permanent personal injuries.

110. The Defendants knew and had reason to know that Plaintiff, Plaintiff's health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by Defendants, and would not have prescribed and implanted same, if the true facts were known to them. In the alternative, CPMC had the ability to determine the true facts but, because its agents and employees were not properly trained to investigate and determine the dangerous propensities of the BRF, they wrongfully failed to determine the true facts and implanted the BRF in Plaintiff's body as a result of said failure to discover true facts.

111. The Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who are implanted with the BRF.

112. At the time Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff used the BRF, Plaintiff and Plaintiff's health care providers were unaware of said Defendants' negligent misrepresentations and omissions.

113. Plaintiff, Plaintiff's health care providers and the general medical community reasonably relied upon misrepresentations and omissions made by Defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the BRF.

114. Plaintiff and Plaintiff's health care provider's reliance on the foregoing misrepresentations and omissions by Defendants' were the direct and proximate cause of Plaintiff's injuries as described herein.

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EIGHTH CAUSE OF ACTION

BREACH OF FIDUCIARY DUTY

(CPMC AND DOES 1-100 INCLUSIVE)

115. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

116. CPMC, through its own acts and the acts of its physicians, including Dr. Edwin Hassid, Dr. Sung Choi, Dr. William Kuo, Dr. Bertrand Tuan, nurses, officers, directors, attendants, managing agents and other employees, created a fiduciary or special relationship with the Plaintiff when its and its aforementioned agents recommended and advised the insertion of a BRF in Plaintiff, and when it and its agents inserted a BRF in Plaintiff on or about March 2004.

117. The implantation of the BRF in Plaintiff created a danger, which arose from the fiduciary or special relationship between CPMC and plaintiff.

118. CPMC therefore had an ongoing duty to warn the Plaintiff of newly-discovered risks related to this danger based on its fiduciary and special relationship with the Plaintiff.

119. On August 9, 2010, the FDA issued a warning letter regarding IVC filters, reporting 921 adverse events associated with the devices. The FDA advised that the events could be related to a retrievable filter remaining in the body for long periods of time.

120. These 921 adverse events had all occurred at various times prior to August 9, 2010, and those events involving the BRF were known to Bard as the devices manufacturer. During the period between the implantation of the device in Plaintiff in 2004 and the date of the FDA warning, Bard wrongfully failed to communicate information regarding the known or knowable defects in the BRF to CPMC or to Plaintiff as they learned it or, in the alternative, CPMC, via its physicians, directors, officers, nurses and employees received the information and wrongfully failed to communicate it to Plaintiff or to take reasonable reactive action.

121. The FDA advised treaters to consider the risks and benefits of filter removal for each patient.

122. CPMC did not advise the Plaintiff of the FDA warning or of the association of adverse events with a retrievable IVC filter remaining in the body for a long period of time, even

though the BRF had already been in the Plaintiff's body for over 6 years when the warning was issued.

123. CPMC did not contact the Plaintiff to obtain information or to advise testing to gather all possible information on the severe dangers to which they knew the Plaintiff was exposed.

NINTH CAUSE OF ACTION

NEGLIGENCE – RECALL/RETROFIT

(ALL DEFENDANTS AND DOES 1-100 INCLUSIVE)

124. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

125. Defendants manufactured, distributed and sold the BRF.

126. Defendants knew or reasonably should have known that the BRF was dangerous or was likely to be dangerous when used in a reasonably foreseeable manner.

127. On August 9, 2010, the FDA issued a warning letter regarding IVC filters, reporting 921 adverse events associated with the devices. The FDA advised that the events could be related to a retrievable filter remaining in the body for long periods of time.

128. The FDA advised treaters to consider the risks and benefits of filter removal for each patient.

129. After learning of this defect, Defendants did not advise the Plaintiff of the FDA warning or of the association of adverse events with a retrievable IVC filter remaining in the body for a long period of time, even though the BRF had already been in the Plaintiff's body for over 6 years when the warning was issued.

130. The Defendants did not contact the Plaintiff to obtain information or to advise testing to understand the severe dangers to which they knew the Plaintiff was exposed.

131. The Defendants did not take available actions to recall the BRF from the market.

132. A reasonable manufacturer, distributor, seller or health care provider, under the same or similar circumstances, would have recalled the BRF after obtaining knowledge of its defective condition.

133. Plaintiff Wayne Ruden was harmed by this conduct. Portions of the fractured BRF remain in Plaintiff's body, including his heart, to this day.

134. Defendants' failure to recall the BRF was a substantial factor in causing Plaintiff Wayne Ruden's harm.

PUNITIVE DAMAGES ALLEGATIONS

(ALL DEFENDANTS AND DOES 1-100 INCLUSIVE)

135. Plaintiff re-alleges each and every allegation in this Complaint and incorporates each allegation into this Count, as if set forth at length, in its entirety.

136. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total reckless disregard for the public safety and welfare.

137. To date, the FDA has issued multiple warnings regarding the BRF and discovery will demonstrate that prior to 2004, Defendants had knowledge of, and were in possession of evidence which shows, the BRF was defective and unreasonably dangerous and had a substantially higher failure rate than did other similar devices on the market. Defendants did not implement adequate measures to rectify the known defects in the BRF.

138. All Defendants, including their managing agents, physicians (as set forth above), employees, officers and directors, failed to:

a. Withdraw the BRF from the market as soon as they learned of its excessive dangers;

b. Withdraw the BRF from the market once the FDA issued its warning letter;

c. Inform or warn Plaintiff or his health care providers of the excessive dangers prior to or after the insertion of the BRF into his body;

d. Plaintiff's health care providers, including CPMC, its managing agents, officers, directors, physicians employed and/or associated with CPMC, including but not limited to Dr. Edwin Hassid, Dr. Sung Choi, Dr. William Kuo, Dr. Bertrand Tuan and employees failed to inform Plaintiff of the dangers associated with the BRF that were known, or knowable, at the time of the operation;

e. Establish and maintain an adequate quality and post-market surveillance system; including, but not limited to, informing BRF patients of the defects inherent in the devices;

f. Timely inform the Plaintiff that the FDA had issued a warning for the BRF; and,

g. Inform patients that the FDA issued a further warning in July 2015 to Defendants regarding their defective IVC components.

139. Defendants so acted to serve their own pecuniary interests. Having reasons to know and consciously disregarding the substantial risk that their product might kill or significantly harm patients, or significantly injure and impair the rights of others, Defendants consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons. With full knowledge of the potential risk of death or permanent harm, Defendants acted with malice, fraud and oppression to warrant punitive damages.

140. Alternatively, Defendants recklessly and willfully pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

141. As a direct, proximate, and legal result of Defendants' acts and omissions as described herein, and Plaintiff implantation with Defendants' defective product, Plaintiff has suffered, and will continue to suffer, serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses as a direct and proximate result of Defendants' willful, malicious, oppressive and fraudulent acts.

PRAYER FOR DAMAGES

WHEREFORE, Plaintiff, Wayne Ruden, prays for relief on the entire complaint, as follows:

a. Judgment to be entered against all defendants on all causes of action of this Complaint, including but not limited to:

1. Physical pain and suffering in the past and which, in reasonable probability, he will continue to suffer in the future;
2. Physical impairment and incapacity in the past and which, in reasonable

probability, he will continue to suffer in the future;

3. Mental anguish in the past and which, in reasonable probability, he will sustain in the future;
4. Reasonable and necessary medical expenses for treatment received in the past and, based upon reasonable medical probability, the reasonable medical expenses he will need in the future;
5. Disfigurement in the past and which, in reasonable probability, he will continue to suffer in the future;
6. Loss of earning capacity in the past and future; and,
7. Punitive damages.

b. Plaintiff be awarded full, fair, and complete recovery for all claims and causes of action relevant to this action;

c. Plaintiff be awarded all appropriate costs, fees, expenses, and pre-judgment and post judgment interest pursuant to the laws of the State of California as authorized by law on the judgments entered in Plaintiff's behalf; and,

d. Such other relief the court deems just and proper.

Dated: December 3, 2015

ONGARO PC

By: _____
GLEN TURNER
Attorneys for Defendants
HONEYWELL INTERNATIONAL INC f/k/a AlliedSignal Inc., Successor-in-Interest to The Bendix Corporation